

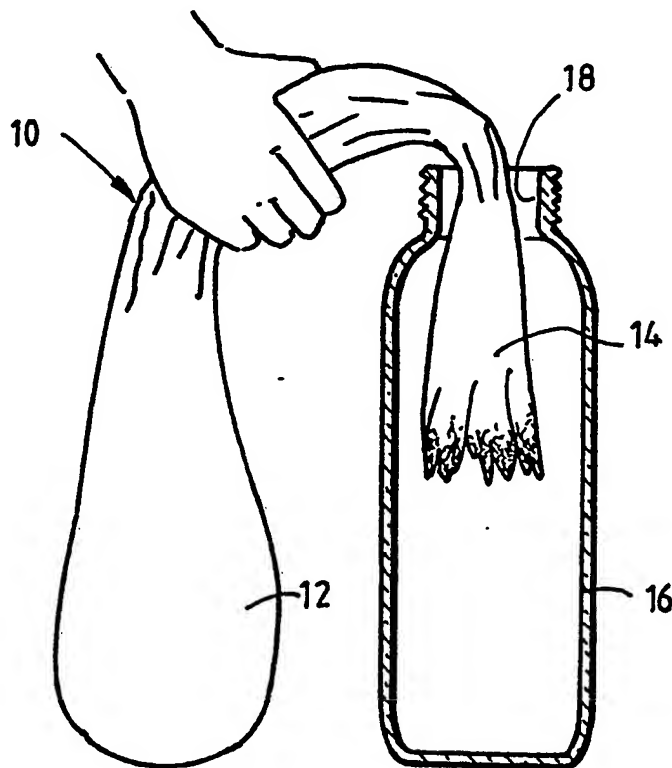


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: DISPOSABLE INSERTS FOR NURSING BOTTLES**(57) Abstract**

A system for feeding infants with an artificial formula includes the supply of a formula (20) into a bag (10) under sterile conditions. The bag (10) is not completely filled with formula (20), the formula (20) occupying one portion (12) with another portion (14) being collapsed as a result of withdrawal of air therefrom. The bag (10) is sealed. In use, the collapsed portion (14) of a bag (10) is inserted into a nursing bottle (16) and the formula (20) caused to flow into the collapsed portion (14) located within the bottle (16). The former filled portion (12) is removed to provide an opening to the formula (20) in the bag (10), and the free end is located between a cap (26) holding a teat (28) and the neck (18) of the bottle (16). The formula (20) may have an increased initial vitamin content to allow for loss of vitamins during storage.



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1 DISPOSABLE INSERTS FOR NURSING BOTTLES

2 This invention relates to the nursing of infants.

3 For the first six months of a baby's life, its sole
4 source of nourishment is milk. This can be:

5 - breast milk exclusively;

6 - breast milk complimented with an artificial formula;

7 or

8 - an artificial formula exclusively;

9 After six months, other foods may be introduced, but
10 milk still forms a major part of a child's diet for at least
11 a further year.12 The incidence of breastfeeding of infants in the State
13 of Victoria, Australia, showed a dramatic drop between 1950
14 to 1970 but since then has been climbing steadily due to:15 - the active encouragement of breastfeeding in
16 hospitals;17 - literature supplied to mothers promoting
18 breastfeeding; and19 - the efforts of such organisations as the Nursing
20 Mothers' Association of Australia.21 Where an infant in the sub-six months of age group is
22 not completely breastfed, it is generally considered to be
23 essential that it be fed on an appropriate commercial infant
24 formula. These formulae are scientifically designed to
25 resemble human milk as closely as technology will permit,
26 and stringent standards have been prescribed for their
27 manufacture.28 Such formulae are dispensed to infants in nursing
29 bottles. Conventional nursing bottles have a glass or
30 plastic body portion, and a closure in the form of a screw-
31 threaded cap into which a teat is fitted.32 All literature on infant feeding stresses the need for
33 sterility in the ingredients and equipment used for making
34 up an artificial feed, whether it be a proprietary formula
35 or ordinary milk.36 Two methods are normally used to sterilise bottles and
37 teats. The equipment can either be immersed in a chemical
38 sterilising solution for one hour, or may alternatively be

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1 plac d in a suitable container, covered with water, brought
2 to the boil and allowed to boil continuously in the water
3 for ten minutes and then cooled. Great care must then be
4 taken to ensure that all sterilised objects remain sterile.

5 Instructions supplied with all dried or concentrated
6 infant formulae require the water which is to be added to
7 reconstitute the formula to be boiled for at least ten
8 minutes. The water will then take an hour or so to cool to
9 body temperature. The powder or concentrate itself is kept
10 in a sterile container which is usually fitted with a
11 plastic lid which must itself be kept sterile. The contents
12 are removed with a scoop which should also be sterilised and
13 dried before use.

14 Since milk is a perfect medium for the growth of
15 bacteria, prepared feeds are required to be kept under
16 refrigeration.

17 Before being fed to the baby the feeds need to be
18 heated to bring it to at least room temperature and, if
19 preferred, to body temperature. This can take several
20 minutes during which time the parent is usually listening to
21 a crying baby.

22 Thus, conventional artificial formulae feeding
23 arrangements have disadvantages compared to breastfeeding.
24 Breast milk is sterile, it requires no preparation, it has
25 no storage problems, it does not need to be warmed before
26 feeding is able to commence, it contains all vitamins,
27 minerals and nutritional value required, and it is readily
28 available.

29 Despite the foregoing problems artificial feeding does
30 have distinct advantages

31 (a) Feeding duties can be shared

32 - the mother does not have to wake up for each night
33 feed;

34 - the mother does not have to take the baby with her to
35 work, to a social function or elsewhere where breastfeeding
36 may not be practicable;

37 - the child can be left with a baby sitter to give the
38 mother more freedom.

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1 (b) The mother knows precisely how much the baby takes in
2 each feed.

3 (c) Some mothers choose not to breastfeed

4 - some women find it distasteful or messy;

5 - some women are unable to breastfeed or have
6 difficulty breastfeeding because of some physical problem.

7 Thus, a feeding system which can eliminate or minimise
8 the problems of artificial feeding will obviously benefit a
9 great many people. Some efforts have been made to provide
10 improved feeding arrangements, but these have not been
11 successful.

12 In addition, most babies suffer from colic. In the
13 case of bottle-fed babies this is occasionally caused or
14 contributed to by the baby sucking against the vacuum in the
15 feeding bottle.

16 To cope with this problem manufacturers recommend that
17 the plastic closure on a nursing bottle that holds the teat
18 should be left slightly untightened so as to admit air into
19 the bottle as the baby sucks. In practice, however this
20 system does not always work well and milk often leaks from
21 the cap of the bottle during feeding.

22 A number of manufacturers have produced bottles
23 specifically designed to overcome this problem but they are
24 expensive and inconvenient to use. For example, Australian
25 patent application no. 77971/75 to Hammer proposes the use
26 of flexible bags for containing nursing liquids, to be used
27 within a particular outer structure, but such an arrangement
28 is costly, in that all the elements of the arrangement must
29 be purchased to replace existing bottles.

30 US-A-3,762,542 to Grimes discloses the use of
31 presterilised bags for insertion into a conventional
32 'nursery'. However, with such a system there is still scope
33 for contamination of the formula dispensed into the bag.

34 It is an object of this invention to provide an
35 improved system for feeding infants with artificial feeding
36 formula.

37 The invention provides an infants' feeding system
38 including a bag (10) containing a feeding formula (20) said

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1 bag (10) having been filled in sterile conditions, said
2 filled bag (10) having only a first portion (12) thereof
3 occupied by said formula (20), a second portion (14) of
4 which is collapsed due to the withdrawal of air therefrom,
5 said second portion being capable of being inserted into a
6 rigid container (16) such that the formula (20) may be
7 caused to flow into said second portion (14) located within
8 said container (16).

9 The invention also provides a method of producing a
10 flexible container containing infants' formula (20),
11 including the steps of partially filling an open-ended
12 flexible container, partially filling said container with
13 infants' formula (20), evacuating air from the remainder of
14 said container to provide a collapsed portion thereof, and
15 sealing said open end.

16 The invention further provides a sealed bag (10)
17 containing infants' formula (20) and including a collapsed
18 portion (14) for insertion into a container (16).

19 An embodiment of the invention will be described in
20 detail hereinafter, with reference to the accompanying
21 drawings, in which:-

22 Figure 1 is a perspective view of a bag filled with
23 infant feeding formula;

24 Figure 2 is an elevation of a nursing bottle into which
25 one end of the bag of Figure 1 is being located;

26 Figure 3 is an elevation of the nursing bottle of
27 Figure 2 showing the liquid in the bag being transferred to
28 the portion of the bag located in the bottle;

29 Figure 4 is an elevation of the bottle and bag of
30 Figure 3, showing the bag about to be cut; and

31 Figure 5 is an elevation of a nursing bottle ready for
32 use.

33 In the embodiment of the invention an artificial
34 infants' feeding formula is prepared in sterile conditions
35 and is packed in a disposable bag 10 (Figure 1) which
36 preferably has the dimensions 180mm (circumference) by 330mm
37 (length).

38 It is considered that as most plastics materials are

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1 highly permeabl to oxyg n they would be unsuitabl for us
2 in forming a bag 10 because over the anticipated shelf life
3 of the formula contained therein, the vitamin content,
4 particularly of vitamin C and folic acid, would drop
5 dramatically.

6 In order to compensate for this loss by boosting the
7 vitamin content before manufacture so as to arrive at an
8 acceptable vitamin content at the end of the contemplated
9 shelf life, the result would be an unacceptably high vitamin
10 level at the start of the shelf life period. The solution
11 is to use a plastic material with a minimum permeability.
12 Special plastic laminates are manufactured for this purpose
13 and are used with the Intasept (referred to hereinafter) and
14 other systems. It is also possible for such a laminate to
15 be produced in a tubular form by an extrusion or other
16 process.

17 Referring to Figure 1, a single feed, that is, a
18 predetermined volume of liquid formula, is packed into each
19 bag 10 in sterile conditions using a UHT (ultra high
20 temperature) process which is used by the produce dairy
21 products having long shelf life at ambient temperatures.

22 The manufacturing process involves -

- 23 1. Mixing the formula;
- 24 2. Sterilising the mixed formula;
- 25 3. Packing the mixed formula into bags 10;
- 26 4. Packing the bags 10 into boxes

27 Steps 1 and 4 will require a relatively simple plant.
28 Step 2 will require the use of a UHT sterilising machine
29 adjusted to the requirements of the product.

30 The greatest risk of contamination arises when the
31 product leaves the UHT sterilising machine and enters the
32 plastic bag 10. At this stage, assuming that the machine
33 has been correctly adjusted and operated, the product should
34 be sterile. The critical component is therefore the packing
35 machine.

36 Because the product is intend d for babies a high
37 degree of reliability in the manufacturing process is
38 essential. A one-in-five thousand failure rate, although

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1 possibly acceptable for UHT household milk, is not good
2 enough. Either an aseptic packaging machine will be
3 required for this particular application or alternatively,
4 an existing machine with a high degree of reliability will
5 need to be adapted.

6 The "Intasept" aseptic 2-30 litre filler manufactured
7 by Wrightcel Limited is claimed to have a high degree of
8 reliability and can be very easily adapted to this
9 application with a minimum of cost.

10 The feed only occupies bottom section 12 of bag 10 and
11 the remainder 14 of the bag has the air evacuated therefrom.
12 Immediately after filling, the bag is sealed by conventional
13 means to prevent any contamination.

14 The size of the feed packaged in this way would depend
15 upon the age of the baby. It is suggested that the feeds
16 would be marketed in a 150 millilitre size and a 250
17 millilitre size. The size of the bag 10, however, would
18 preferably remain the same.

19 The filled bags are then packed in cardboard boxes or
20 the like, containing a given number of feeds to each box.

21 Being sterile, these boxes of infant feeds could be
22 sold "off the supermarket shelf" and would not require
23 refrigeration. The anticipated shelf life is three months.

24 Figures 2 to 5 inclusive demonstrate the manner in
25 which a feed is prepared after a filled bag 10 has been
26 purchased by a parent.

27 The parent would obtain a filled bag 10 from a cupboard
28 or other storage area.

29 As shown in Figure 1, the parent would then insert the
30 collapsed end 14 of bag 10 into the open end 18 of a
31 conventional nursing bottle 16. The parent then raises
32 filled end 12 of the bag 10 (Figure 3) so that the infants'
33 formula 20 flows in the direction of the arrows to end 14,
34 which is located in bottle 16. The formula 20 is then
35 within the bottle 16, but is separated therefrom by the
36 material from which bag 10 is formed.

37 The former bottom portion 12 of the bag 10 which now
38 protrudes above the neck 18 of the bottle 16 is now

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1 substantially devoid of milk, and the outer portion of this
2 is cut off with scissors or the like 22 to form an open-
3 ended bag leaving, preferably at least sixty millimetres of
4 the bag 10 protruding above the neck of the bottle (Figure
5 3).

6 The sides 24 of this open bag are now pulled down over
7 the outside of the neck 18 of the bottle 16 (Figure 4) and a
8 cap 26 holding a teat 28 is screwed onto the neck 18 of
9 bottle 16, clamping the sides 24 between it and the neck 18.
10 Thus, the bottle 16 is now ready for the formula to be
11 dispensed to the infant.

12 It will be observed that the system of this invention
13 has the following advantages:-

14 (a) The bottle does not require sterilisation, because
15 no part of the milk touches it.

16 (b) The feed does not need to be heated since it is
17 already at room temperature. If it is desired to bring the
18 feed to blood temperature, only minimal heating is required.

19 (c) An unlimited number of feeds can be taken in the
20 car, camping, on picnics or elsewhere where sterile
21 facilities for the preparation of feeds are not available.
22 All that is required is a jar or other small container of
23 sterilising solution for the teat and screw on cap.

24 (d) The mother can be certain that the feed is
25 completely sterile because there is no possibility of
26 contamination.

27 (e) The system fits all commonly used feeding bottles
28 without any modification required.

29 (f) If a hole is made in the feeding bottle, the bag
30 10 will collapse like the inside of a wine cask as the baby
31 feeds. Since the baby does not have to suck against a
32 vacuum, the chances of colic are diminished.

33 It is considered that the formula packed in bags 10
34 will need to be initially boosted with vitamins,
35 particularly vitamins A, C and folic acid, which will be
36 lost:

37 - due to the heat of the UHT process;

38 - due to oxygen contamination during storage; or

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1 - du t the effect of light.
2 Losses du to light can be minimised by packing the bags
3 into an appropriate box. Oxygen contamination can be
4 minimised by using an appropriate plastic laminate for the
5 bags, as discussed hereinbefore.
6 The claims form part of the disclosure of this
7 specification.

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1 CLAIMS:

- 2 1. An infants' feeding system including a bag (10)
3 containing a feeding formula (20) said bag (10) having been
4 filled in sterile conditions, said filled bag (10) having
5 only a first portion (12) thereof occupied by said formula
6 (20), a second portion (14) of which is collapsed due to the
7 withdrawal of air therefrom, said second portion being
8 capable of being inserted into a rigid container (16) such
9 that the formula (20) may be caused to flow into said second
10 portion (14) located within said container (16).
- 11 2. An infants' feeding system according to claim 1,
12 wherein said container (16) is a nursing bottle (16).
- 13 3. An infants' feeding system according to claim 1 or
14 claim 2, wherein said first portion (12) is removed to
15 provide access to said formula (20) when said second portion
16 (14) is filled and located within said container (16) and
17 wherein said open end may be trapped between a neck (18) of
18 said container and dispensing apparatus (26, 28) for said
19 formula (20).
- 20 4. An infants' feeding system according to claim 3, where-
21 in said dispensing apparatus (26,28) includes a teat (28).
- 22 5. An infants' feeding system according to any preceding
23 claim, wherein said formula (20) has an initial boosted
24 vitamin content.
- 25 6. A method of producing a flexible container containing
26 infants' formula (20), including the steps of partially
27 filling an open-ended flexible container, partially filling
28 said container with infants' formula (20), evacuating air
29 from the remainder of said container to provide a collapsed
30 portion thereof, and sealing said open end.
- 31 7. A method according to claim 6, wherein said open-ended
32 flexible container is a substantially tubular member having
33 one open end and being formed from a minimum-permeability
34 plastics laminate material.
- 35 8. A sealed, sterile bag (10) containing infants' formula
36 (20), when produced by the method of claim 6 or 7.
- 37 9. A sealed sterile bag (10) substantially as herein
38 described with reference to the accompanying drawings.

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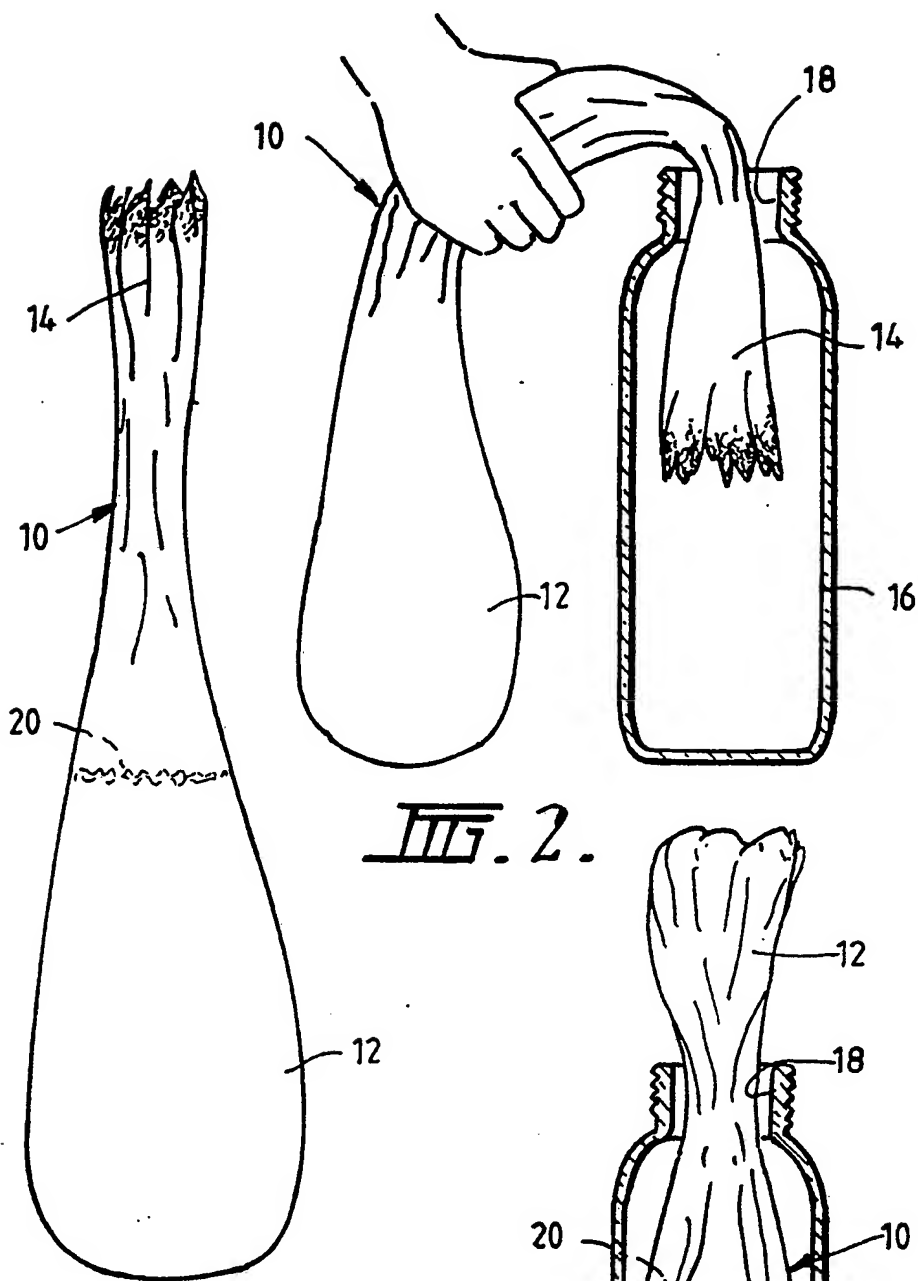


FIG. 2.

FIG. 1.

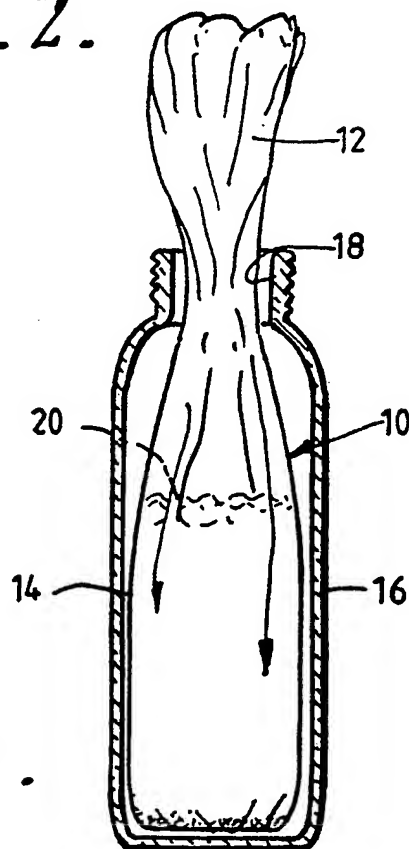
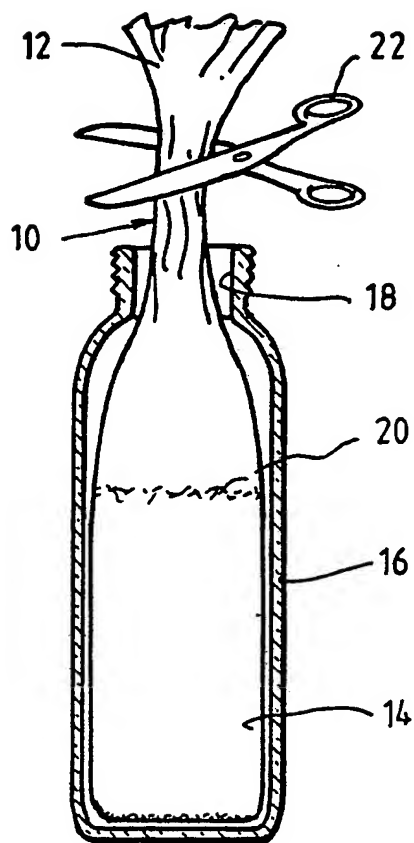
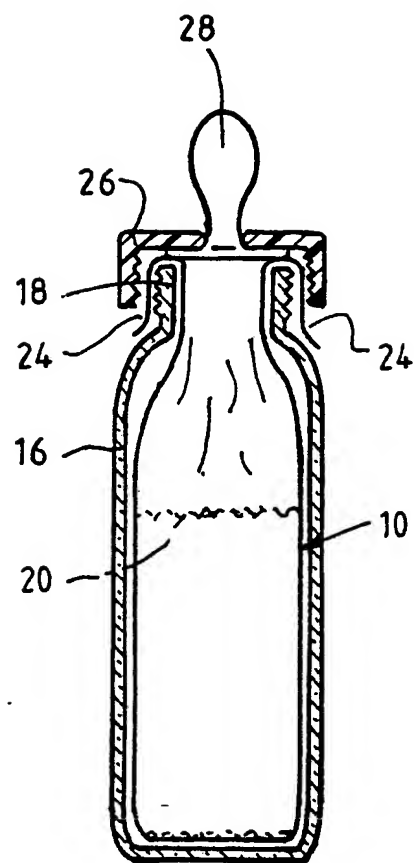


FIG. 3.

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FIG. 4.FIG. 5.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/AU 87/00198

I. CLASSIFICATION F SUBJECT MATTER (If several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.⁴ A61J 9/00, 9/08 // A23C 3/023, B65B 29/00

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System

Classification Symbols

IPC

A61J 9/00, 9/08, A23C 3/023

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	AU,A, 65873/65 (McKENNA) 4 May 1967 (04.05.67) (See p.5, 1.22 - p.8, 1.23; Claims; Drawings)	
A	AU,B, 246/66 (CONTINENTAL CAN CO., INC.) 13 July 1969 (13.07.69)	
A	AU,A, 17756/70 (PERLMAN) 10 February 1972 (10.02.72) (See Claims 1,10)	
A	US,A, 3507666(CHENEY et al) 21 April 1970 (21.04.70)	
A	US,A, 3593871 (BUNDY) 20 July 1971 (20.07.71)	
A	AU,A, 77971/75 (HAMMER) 12 August 1976 (12.08.76) (See p.5, 1.32 - p.8, 1.32)	
A	AU,A, 25112/77 (GRACE) 16 November 1978 (16.11.78)	
A	EP,A, 129326 (FRES-CO SYSTEM USA, INC.) 27 December 1984 (27.12.84)	
A	WO,A, 85/04571 (BAXTER TRAVENOL LABORATORIES, INC.) 24 October 1985 (24.10.85)	
A	WO,A, 85/04574 (BAXTER TRAVENOL LABORATORIES, INC.) 24 October 1985 (24.10.85)	
A	WO,A, 85/04575 (BAXTER TRAVENOL LABORATORIES, INC.) 24 October 1985 (24.10.85)	

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"A" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

22 September 1987 (22.09.87)

Date of Mailing of this International Search Report

(09.10.87) 9 OCTOBER 1987

International Searching Authority

Australian Patent Office

Signature of Authorized Officer

[Signature] A. HENDRICKSON

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 87/00198

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members		
AU 17756/70	US 3578239	US 3716369		
EP 129326	US 4518087	US 4576285	US 4667453	
WO 8504571	EP 179846	ZA 8502695		
WO 8504574	ZA 8502699			
WO 8504575	EP 176569	ZA 8502700		

END OF ANNEX